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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/819,305	01/09/92	ANDERSON	P 3117-080

EXAMINER: KIM, K

PENNIE & EDMONDS
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ART UNIT	PAPER NUMBER
1813	4

DATE MAILED: 10/15/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on Amend Prelim 1/9/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449. (6 pages)
4. ☐ Notice of informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1 and 90-97 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1 and 90-97 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Newly added claim 92 recites immunogenic conjugates of S. pneumoniae serotype 6A which is not supported by the originally filed specification although use of serotype 6 occurs. See for instance claim 45.

Claim 92 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 90 and 96 are rejected under 35 U.S.C. § 102(e) as being anticipated by Jennings et al 4,356,170.

Jennings et al teach immunogenic conjugate of capsular

polymer from bacterial pathogens such as streptococci, pneumococci or meningococci and bacterial toxin or toxoid such as diphtheria or toxin or tetanus toxoid by reductive amination of oxidized polysaccharides which would inherently possess at least two carbonyl groups. See columns 3-5 of Jennings et al. See particularly column 3, lines 15-22 and 42-51 of Jennings et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 91-95 are rejected under 35 U.S.C. § 103 as being unpatentable over Jennings et al.

The reference does not particularly exemply the use of capsular polymers of the particularly claimed serotypes. Nevertheless, use of the particular serotype polymer in the conjugate of Jennings et al would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made in view of the teachings of Jennings et al for the use of any bacterial source including streptococci or pneumococci with the expected benefit of making the immunogen specific for the serotypes.

Claim 97 is rejected under 35 U.S.C. § 103 as being unpatentable over Jennings et al in view of Uchida et al (1972). Jennings et al do not particularly exemplify the use of CRM 197.

Uchida et al teach CRM 197 mutant of diphtheria toxin which is nontoxic and has same binding sites in HeLa cells as the native toxin.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute CRM197 of Uchida et al in the immunogenic conjugate of Jennings et al since CRM 197 is a functional equivalent to diphtheria toxin of Jennings et al with the expected benefit of nontoxicity taught by Uchida et al.

Claims 1 and 90-97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 and 50; 1-27,30 and 31; 1-8; 1-32;

and 1-34 of U.S. Patent No. 4,673,574; 4,761,283; 4,808,700; 4,902,506; and 5,097,020; respectively. Further, claims 1 and 90-96 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 15-28, 34-44 and 50 of copending application Serial No. 07/205,132. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued patents and the copending application claim species of the conjugates which are generically claimed in the instant application thereby rendering obvious the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Claims 1 and 90-97 are directed to an invention not patentably distinct from claims 1-44 and 50; 1-27, 30 and 31; or 1-3, 15-28, 34-44 and 50 of commonly assigned 4,673,574, 4,761,283 and 07/205,132 for the reasons set forth above.

Commonly assigned 4,673,574, 4,761,283 and 07/205,132, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case

qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

Claim 92 is rejected under 35 U.S.C. § 103 as being unpatentable over Anderson 4,761,283 and 4,762,713 and Anderson et al 4,808,700.

Anderson and Anderson et al disclose and/or claim immunogenic conjugates between capsular polymer fragment and bacterial toxin or toxoid carrier. However, the references do not particularly exemplify the use of polymer fragments from S. pneumoniae serotype 6A. Nevertheless, substitution of the polymer fragments of serotype 6A would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the broad disclosure by the patents for the expected benefit of making immunogen specific to the serotype 6A.

Claim 92 is provisionally rejected under 35 U.S.C. § 103 as being obvious over copending application Serial No. 07/205,132 for the reasons set forth above.

Copending application Serial No. 205,132 has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would

constitute prior art under 35 U.S.C. § 102(e) if patented. This provisional rejection under 35 U.S.C. § 103 is based upon a presumption of future patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 C.F.R. § 1.132 that any unclaimed invention disclosed in the copending application was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention prior to the effective U.S. filing date of the copending application under 37 C.F.R. § 1.131.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The prior art submitted as PTOL FORM-1449 in the parent 07/423,081 is made of record.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PLO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay K. Kim, Ph. D. whose telephone number is (703) 308-3881.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Kim/sg
October 14, 1992
October 15, 1992

Kay K. Kim

KAY K. KIM
PATENT EXAMINER
GROUP 1800